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Standards Worldwide

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Comments of ASTM International

FR Doc No: 2012-7602

April 15, 2012

“Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”

ASTM International (ASTM) is pleased to submit these comments in response to the Office of Management and Budget (OMB) request for interested parties to provide input on current issues regarding Federal agencies' standards and conformity assessment related activities.

ASTM International

ASTM is a leading, non-profit organization devoted to the development of voluntary consensus standards. For more than 100 years, ASTM has served society by providing a global forum for the development and publication of voluntary consensus standards for materials, products, systems, and services that are utilized by ninety industrial sectors in the United States and in most geographic regions of the world. ASTM is accredited by the American National Standards Institute (ANSI) and meets the World Trade Organization's (WTO) six principles¹ for the development of international standards.

Over 30,000 individuals from 135 countries, including manufacturers, retailers, consumers, regulators, academics and researchers, serve on ASTM's 143 technical committees. Within ASTM's technical committees, members develop standards in areas such as consumer products, medical services and devices, textiles, metals, paints, plastics, petroleum, construction, aviation, energy, water, and the environment. ASTM's diverse array of standards are used around the world to improve product quality, enhance safety, facilitate market access and trade, and build consumer confidence.

Over 1,400 individuals from federal agencies are actively engaged in 90 percent of ASTM's standards writing technical committees. While nearly every federal agency participates, the agencies with the most representation in ASTM's standardization work

¹ G/TBT/1/Rev. 10, Annexes to Part 1.B, para. 1; WTO's *Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement*. This framework for quality, international technical standards consists of six principles: transparency, openness, impartiality and consensus, relevance and effectiveness, coherence and developing country interests.

include the Department of Defense (305 ASTM members), the Department of Commerce (198 ASTM members), the Department of Health and Human Services (133 ASTM members) and the Environmental Protection Agency (112 ASTM members).

OMB Review Questions

1. *Are Federal agencies generally following the guidance set out in the Circular and providing an adequate explanation of how they considered standards and conformity assessment-related issues in the preambles to rulemakings?*

In ASTM's experience, we have found that agencies generally follow the guidance set out in the Circular in explaining standards issues in the preambles to rulemaking.

2. *Is lack of access to standards incorporated by reference in regulation an issue for commenters responding to a request for public comment in rulemaking or for stakeholders that require access to such standards? What are the best practices for providing access to standards incorporated by reference in regulation during rulemaking and during the effective period of the regulation while respecting the copyright associated with the standard?*

ASTM strives to be flexible and reasonable when working with federal agencies and the regulated public on access issues. When a federal agency proposes to incorporate (by reference) an ASTM standard in rulemaking, ASTM engages with the agency to provide the public with read-only access to the standard during the public comment period associated with the rulemaking. An agency seeking public access to an ASTM standard during the public comment period of a rulemaking should send a letter to ASTM that explains the details of the public comment period and the specific ASTM standard(s) to be included in the proposed rule.

As an example, ASTM is currently providing public access via a link to an ASTM webpage for a consumer product safety related standard (ASTM F406-11) that has been proposed to be incorporated by reference by the Consumer Product Safety Commission as part of CPSC docket number 2011-0064. As stated in the proposed CPSC rule:

“In this document, the Commission proposes a safety standard for play yards. The proposed standard is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F 406–11, “Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards” (“ASTM F 406–11”). The ASTM standard is copyrighted but can be viewed as a read-only document, only during the comment period on this proposal, at <http://www.astm.org/cpsc.htm>, by permission of ASTM.”

ASTM has worked with other agencies to provide similar access, including ASTM environmental and health safety related standards proposed to be referenced in rulemakings by the Environmental Protection Agency. ASTM recommends this approach to OMB for consideration as a best practice.

3. *What are the best practices for incorporating standards by reference in regulation while respecting the copyright associated with the standard?*

Virtually all governmental agencies depend on voluntary consensus standards to fulfill their important mission and to meet the demands of their stakeholders. ASTM finds that — as a best practice — government agencies should respect the intellectual property of standards development organizations by referencing a specific voluntary consensus standard in a regulation and provide the public with information on how to obtain a copy of it. In general, the long-standing federal policy of incorporation by reference has been closely examined over the years and was recently reaffirmed by the White House’s National Science and Technology Council (Subcommittee on Standards) and the Administrative Conference of the United States (an independent federal agency dedicated to improving the administrative and regulatory process).

4. *What resources and other costs are involved in the development and revision of voluntary standards?*

The development of voluntary consensus standards is a complex and resource-intensive process that involves, among other things, a professional staff, the housing and administration of the process, planning and execution of committee meetings and a state of the art technology infrastructure that facilitates the collaboration and participation of global participants; balloting and comment resolution; and document editing, publication and distribution. For organizations such as ASTM, there are also significant costs of achieving and maintaining accreditation by the American National Standards Institute (ANSI) and for engaging policy related activities within a global standards community. To facilitate more effective participation by consumer safety advocates in our standards development process, ASTM often waives their membership fees and regularly provides travel and participation assistance to critical meetings. Finally, as part of our commitment to our mission and global stakeholders, ASTM offers support to developing countries by providing access to ASTM standards, technical assistance related to the application of ASTM standards, the opportunity to participate in the ASTM standards development process, and travel funds to facilitate meeting attendance. In summary, ASTM’s commitment to the development and maintenance of standards requires significant resources that continue to increase as process efficiencies, product diversification, and state-of-the-art technologies evolve.

5. *What economic and other factors should agencies take into consideration when determining that the use of a voluntary standard is practical for regulatory or other mission purposes?*

In today’s domestic marketplace, there are 224 organizations that are accredited by the American National Standards Institute (ANSI) to develop standards. Quite simply, it’s hard to imagine an instance where an agency would need to forgo collaborating with an accredited SDO to develop voluntary consensus standards of relevance to their regulatory interests. From an economic standpoint, embarking upon a government-unique approach toward developing standards could cost taxpayers millions of dollars and force the federal government to shift its limited resources away from other mission-critical programs.

Furthermore, such a shift in cost would be detrimental due to the intrinsic value of the current U.S. standards development process, which brings together all stakeholders—public and private bodies—in the development of relevant consensus standards. This system of public/private partnership in the collaborative development of voluntary consensus standards is the envy of the world and could not be replicated by the government.

As far as choosing voluntary consensus standards for regulatory or other mission purposes, the most important factor for an agency to consider is the technical quality and merit of the standard and the ability of the standard to assist the agency in achieving its objectives. The flexibility to choose standards based on important considerations such as technical quality, market relevance, and global coherence often results in the utilization of standards that best match the emerging regulatory need.

6. *How often do standards-developing bodies review and subsequently update standards? If standards are already incorporated by reference in regulations, do such bodies have mechanisms in place for alerting the relevant agencies and the public, especially in regard to the significance of the changes in the standards?*

In ASTM, each technical subcommittee is responsible for the maintenance of the standards under its jurisdiction. Subcommittees can update or revise their standards at any time and as often as they deem appropriate. This flexibility allows subcommittees to react quickly to advances in technology and to accommodate other industry changes. The *ASTM Regulations Governing ASTM Technical Committees* requires that at a minimum, subcommittees review each standard under their jurisdiction during the fourth year after the last approval date and conduct a ballot for revision, reapproval, or withdrawal within five years of the last approval date. If a standard has not received a new approval date by the end of the eighth year, it is automatically withdrawn from publication.

ASTM has implemented an automated email notification system for government agencies, code bodies or other organizations who are interested in being informed about revisions or reapprovals to ASTM standards that they rely upon. To take advantage of this service, the agency or organization just needs to provide the list of relevant standards to ASTM. For example, the CPSC references numerous ASTM standards including ASTM F1169, Consumer Safety Specification for Full-Size Baby Cribs, in 16 CFR Parts 1219 and 1220 to satisfy the requirements in Section 104 of the Consumer Product Safety Improvement Act of 2008. Whenever F1169 or any other standard they reference is revised or reapproved, the appropriate CPSC engineer is notified and offered a redlined standard which identifies the changes to the new approved version. Any organization interested in receiving tailored updates for specific standards can contact ASTM to arrange for this custom notification.

The ASTM Standards Tracker Alert is a free public email notification service that helps interested stakeholders stay up-to-date on recently approved standards, revisions to existing standards and initiation of the development of new work items. Interested individuals can tailor their alerts to individual standards or broaden their alerts for industry segments or a particular ASTM committee.

7. *Should OMB set out best practices on how to reference/incorporate standards (or the relevant parts) in regulation? If so, what are the best means for doing so? Are the best means of reference/incorporation context-specific? Are there instances where incorporating a standard or part thereof into a regulation is preferable to referencing a standard in regulation (or vice versa)?*

ASTM finds that — as a best practice — government agencies should continue to respect the intellectual property of standards development organizations by referencing a specific voluntary consensus standard in a regulation and provide the public with information on how to access it. Whether an agency chooses to include all or a specific section of a standard in the regulation is a determination best made by the agency. In either case, incorporation by reference is the best way to utilize standards or relevant parts of standards in regulations.

8. *Should an OMB supplement to the Circular set out best practices for updating standards referenced in regulation as standards are revised? If so, what updating practices have worked well and which ones have not?*

There are 1,400 ASTM standards referenced over 2,200 times in federal regulations. The majority of these references are out of date – many woefully so. In the important area of toy safety, Congress has recognized the critical need for the CPSC to adopt and enforce the most recent version of ASTM F963, Standard Consumer Safety Specification for Toy Safety. Revisions to this standard are made frequently due to changes in technology and materials, previously unforeseen uses of such products, and new hazards identified in the marketplace. The Consumer Product Safety Improvement Act of 2008 creates a mechanism that requires the CPSC to review every revision to F963 published by ASTM. CPSC has 90 days after publication to reject revisions – in whole or in part. Otherwise, the most recent version of ASTM F963 becomes the mandatory rule 180 days after its publication. More recently, Congress chose to utilize this same revision policy in P.L. 112-28 and apply it to a broad category of standards for durable infant products. In summary, this approach has worked well as it provides a mechanism for the most recent version of a standard incorporated by reference to be enforced without the additional time and expense associated with the promulgation of formal rulemaking. OMB should consider mechanisms such as this if it decides to issue best practices for updating standards referenced in regulation.

9. *Do agencies consult sufficiently with private sector standards bodies when considering the update of regulations that incorporate voluntary standards, especially when such standards may be updated on a regular basis?*

Some agencies do a very good job of providing strategic input and engagement in the development and revision of voluntary consensus standards that may be used for regulatory or other mission purposes, but it varies agency-by-agency (and even within different sub-units of agencies). Overall, resources committed to government engagement in the activities of SDOs needs to be enhanced. When agencies are actively engaged in the process, they have early and direct knowledge of proposed revisions as

well as the technical rationale for such revisions. This information can be used to support their regulatory initiatives.

As a good model of “upstream” regulatory engagement in voluntary standards development to address emerging technologies or new hazards in the marketplace, consider the approach of the Consumer Product Safety Commission (CPSC). The CPSC 2011-2016 Strategic Plan details its strategic approach toward engaging in voluntary standards development activities. When CPSC staff identify the need for a voluntary standard or a revision that will advance the objective of protecting the public from the threat of injury or death due to an unsafe consumer product, they submit a recommendation to an SDO based on consumer product incident data and analysis of that data². Typically – and as is the case with ASTM — the SDO organizes a task group to perform a technical assessment and prepares a draft standard (or revision to existing standard) for review and comment. During this comment period, the CPSC staff provides technical assistance and clarifying analyses. After evaluating and incorporating technical comments on the proposal, the task group works with the standards writing committee to achieve approval of the final voluntary standard or revision to existing standard. The CPSC does not hold an official vote per agency policy but provides non voting member commentary that is given full consideration. Once the voluntary standard or revision is approved, it usually becomes the recognized norm for that industry group and product type. This model works extremely well for regulators and stakeholders.

10. Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions?

Federal agencies in the U.S. have the flexibility to choose from a broad portfolio of voluntary consensus standards that best meet their specific regulatory or procurement needs and objectives. Last year, the U.S. Department of Energy (DOE) published a final rule that incorporates by reference into Title 10, Code of Federal Regulations, the following standards: (1) AHRI 1250 (I-P)-2009; (2) ASTM C1363-05; (3) DIN EN 13164:2009-02; (4) DIN EN 13165:2009-02; and (5) NFRC 100-2010. ASTM recommends that OMB should provide guidance to agencies that it is appropriate to allow the use of more than one standard when there is an acceptable level of technical convergence and compatibility in multiple voluntary consensus standards that match the attributes desired by the agency for fulfilling regulatory objectives. By referencing multiple voluntary consensus standards, industry can choose to meet the standard that best matches its product or material, or that best reflects their business objectives.

11. Have there been any developments internationally--including but not limited to U.S. regulatory cooperation initiatives--since the publication of Circular A-119 that OMB should take into account in developing a possible supplement to the Circular?

² Consumer Product Safety Commission 2011-2016 Strategic Plan

ASTM recommends that the U.S. government collaborate with other U.S. stakeholders to do more to help foreign stakeholders understand the benefits of the approach to incorporation by reference embodied in the U.S. standards system. To advance the diverse international standards objectives and interests of U.S. stakeholders, the U.S. government should also continue to seek full implementation of the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement and annexes, as well as decisions taken in the WTO TBT Committee. Currently, the U.S. government is engaged in numerous bi-lateral and multi-lateral fora where international regulatory cooperation and standards are being discussed, including the Transatlantic Economic Council (TEC), Trans Pacific Partnership (TPP), Regulatory Cooperation Council (RCC), Asia Pacific Economic Council (APEC), the U.S.–Mexico Economic Partnership, and others. In these important venues and others, the U.S. government should continue to foster and support the unique character and strengths of the public-private partnership in standards development as it pursues trade and other international agreements, regulatory cooperation, and legislative and regulatory approaches.

12. Are there other issues not set out above that OMB might usefully seek to address in a supplement?

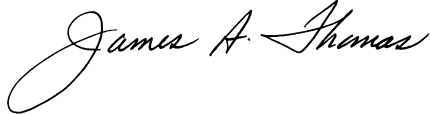
ASTM would like to take this opportunity to reaffirm its interest in working with OMB and others toward the common objective of providing reasonable access to standards incorporated by reference and aligning the needs of the public with the rights of intellectual property holders.

As a non-profit, full consensus SDO, ASTM has deliberately designed its business model to make standards development cost-effective for the government, for the taxpayer, for the stakeholder, and for the user that buys its standards. We develop standards based on the needs of industry, government or society, not on the potential commercial value of the standard as assessed by the SDO. Many ASTM standards development activities break even or lose money, but they support the environment, protect the consumer, or in some other way serve the general welfare of society. Fortunately, the smaller percentage of our standards that generate revenue support our overall activities as part of our mission.

If federal policy moved away from incorporation by reference to an untested alternative model, such an action would lead to many unintended costs and consequences for the public. It would force ASTM's standard development costs upward to the point where broad representation and participation by government agencies would result in impossible constraints on agency budgets. We would have to find other models of standards development and delivery such as charging large project fees, meeting fees, and other front-end costs that we have very deliberately chosen to avoid to date. This would have broad impacts, particularly on the small and medium sized companies, consumer groups, academics and others that have historically benefited from our low membership cost of \$75 per year which provides full participation rights and access to many ASTM standards. In summary, it would defeat the very purpose of the Circular, which is to make government participation in private sector standardization and use of private sector standards economically viable.

Please feel free to contact Jeff Grove in the ASTM Washington Office at (202)223-8505 to discuss ASTM's comments.

Sincerely,

A handwritten signature in cursive script that reads "James A. Thomas". The signature is fluid and elegant, with a large initial 'J' and a distinct 'A'.

James A. Thomas

JAT/mah